

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference LEA36714-WO	<b>FOR FURTHER ACTION</b>		See item 4 below
International application No. PCT/EP2004/011807	International filing date ( <i>day/month/year</i> ) 19 October 2004 (19.10.2004)	Priority date ( <i>day/month/year</i> ) 31 October 2003 (31.10.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant BAYER TECHNOLOGY SERVICES GMBH			

<p>1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.</p>																	
<p>3. This report contains indications relating to the following items:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;"><input checked="" type="checkbox"/></td> <td style="width: 85%;">Box No. I Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII Certain observations on the international application</td> </tr> </table> <p>4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).</p>		<input checked="" type="checkbox"/>	Box No. I Basis of the report	<input type="checkbox"/>	Box No. II Priority	<input type="checkbox"/>	Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI Certain documents cited	<input type="checkbox"/>	Box No. VII Certain defects in the international application	<input type="checkbox"/>	Box No. VIII Certain observations on the international application
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<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</td> <td style="width: 40%;">Date of issuance of this report 27 July 2006 (27.07.2006)</td> </tr> </table>		The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 27 July 2006 (27.07.2006)
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<p>Facsimile No. +41 22 338 82 70</p>	<p>Authorized officer <b>Ellen Moyse</b> e-mail: pt05@wipo.int</p>		

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

*TRANSLATION*

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

		Date of mailing (day/month/year)
Applicant's or agent's file reference <b>LEA36714-WO</b>		FOR FURTHER ACTION See paragraph 2 below
International application No. <b>PCT/EP2004/011807</b>	International filing date (day/month/year) <b>19.10.2004</b>	Priority date (day/month/year) <b>31.10.2003</b>
International Patent Classification (IPC) or both national classification and IPC <b>A61K9/51 , A61 K9/16</b>		
Applicant <b>BAYER TECHNOLOGY SERVICES GMBH</b>		

1. This opinion contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the opinion
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/EP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I	Basis of this opinion
1.	With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item. <input type="checkbox"/> This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2.	With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of: a. type of material <input type="checkbox"/> a sequence listing <input type="checkbox"/> table(s) related to the sequence listing b. format of material <input type="checkbox"/> in written format <input type="checkbox"/> in computer readable form c. time of filing/furnishing <input type="checkbox"/> contained in the international application as filed. <input type="checkbox"/> filed together with the international application in computer readable form. <input type="checkbox"/> furnished subsequently to this Authority for the purposes of search.
3.	<input type="checkbox"/> In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4.	Additional comments:

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Box No. V	<u>Reasoned statement under Rule 43bis.I(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</u>																									
<p><b>1. Statement</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%;">Novelty (N)</td> <td style="width: 50%;">Claims</td> <td style="width: 25%; text-align: right;">YES</td> </tr> <tr> <td></td> <td><u>6</u></td> <td></td> </tr> <tr> <td></td> <td><u>1-5, 7-10</u></td> <td style="text-align: right;">NO</td> </tr> <tr> <td>Inventive step (IS)</td> <td>Claims</td> <td style="text-align: right;">YES</td> </tr> <tr> <td></td> <td><u>1-10</u></td> <td style="text-align: right;">NO</td> </tr> <tr> <td>Industrial applicability (IA)</td> <td>Claims</td> <td style="text-align: right;">YES</td> </tr> <tr> <td></td> <td><u>1-10</u></td> <td style="text-align: right;">NO</td> </tr> <tr> <td></td> <td>Claims</td> <td style="text-align: right;">NO</td> </tr> </table> <p><b>2. Citations and explanations:</b></p> <p><b>1. Documents cited</b></p> <p>Reference is made to the following documents:</p> <p>D1: US-A-5 780 062 (FRANK ET AL) 14 July 1998 (1998-07-14)</p> <p>D2: EP-A-1 344 520 (ACTIPAC BIOSYSTEMS GMBH) 17 September 2003 (2003-09-17)</p> <p>D3: DE-101 51 392 A1 (BAYER CROPSCIENCE AG) 8 May 2003 (2003-05-08)</p> <p>D4: WO 00/33820 A (BASF AKTIENGESELLSCHAFT; HEGER, ROBERT; AUWETER, HELMUT; BREITENBACH) 15 June 2000 (2000-06-15)</p> <p>D5: US-A-4 826 689 (VIOLANTO ET AL) 2 May 1989 (1989-05-02)</p> <p><b>2. Novelty</b></p> <p>The expressions used in claims 1, 2, 5-7, 9, 10 "if appropriate", "more particularly" and "preferably" do not restrict the scope of protection of the claims, that is to say, any feature preceded by such an expression must be considered entirely optional.</p>			Novelty (N)	Claims	YES		<u>6</u>			<u>1-5, 7-10</u>	NO	Inventive step (IS)	Claims	YES		<u>1-10</u>	NO	Industrial applicability (IA)	Claims	YES		<u>1-10</u>	NO		Claims	NO
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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

D1 discloses (see column 4, lines 8-30, the example and claims 1-7) a method for producing small particles having the steps: a) dissolving the active organic compound in a solvent 1 which is miscible with water, b) providing a solution of a polymer (PVP) and an amphiphile (sodium dodecylsulfate) in an aqueous solvent 2 (in which the active compound is insoluble), c) mixing the solutions from steps a) and b) so as to cause a precipitation, and d) freeze drying the suspension.

D2 discloses (see page 8, line 29 - page 9, line 4) a method for producing microparticles and nanoparticles comprising the steps: a) precipitating an active compound in a solution which contains polymer dissolved in a solvent in order to produce a suspension of the active compound, b) mixing the suspension produced with an aqueous surfactant solution and solidifying the polymer.

Although the products obtained in D1 and D2 are not explicitly characterized as amorphous, they are produced by a method according to claim 1 of the present application. If, therefore, the method according to claim 1 leads to the sought-after product, as required by PCT Article 6, the products of D1 and D2 must also be amorphous.

The subject matter of claims 1-5, 7-10 is therefore not novel within the meaning of PCT Article 33(2).

**3. Inventive step (PCT Article 33(3))**

Claim 6 is not considered inventive, since it does not

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appear to contain any technical features which lead to a non-obvious solution of a technical problem (PCT Article 33(3)).

**4. Industrial applicability (PCT Article 33(4))**

The subject matter of claims 1-10 thus meets the requirements of PCT Article 33(4) with respect to industrial applicability.